IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
(HOUSTON DIVISION)

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| GAYATHRI MURTHY,<br>Plaintiff, | §<br>§<br>§ | |
| v. | § | CASE NO. 4:11-cv-00105-KPE |
| ABBOTT LABORATORIES,<br>Defendant. | §<br>§<br>§ | |

**PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

Respectfully submitted,

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Pursuant to Rule 56, FED. R. CIV. P., Plaintiff Gayathri Murthy files this Motion for Partial Summary Judgment. The motion is primarily based on the testimony of Abbott's clinical investigator and prescribing physician, Dr. Jovan Popovich. Based on this undisputed testimony, the Court can readily dispose of two of Abbott's principal defenses: 1) the learned intermediary doctrine, and 2) Section 82.007 of the TEXAS CIVIL PRACTICE AND REMEDIES CODE [hereinafter "CPRC"].[1] With the exception of Dr. Popovich's more recent deposition, many of the evidentiary facts are already before the Court. Consequently, Plaintiff expressly incorporates all previous briefing and exhibits, including her Motion for Relief from Judgment [Doc. 83].

**Introduction and Overview**

The grounds for this motion are straightforward. Dr. Popovich admits that he was paid by Abbott under the auspices of its HERO[2] clinical trial to prescribe Humira to Plaintiff. As Plaintiff previously pled, Dr. Popovich confirms that his medical decisions and related treatment of the Plaintiff, including the dosing regimen for his patient, and the clinical measures he had to use to follow up with the patient, were all expressly dictated by Abbott under the terms of the clinical trial study protocol and agreement. The terms of his agreement with Abbott required him to strictly follow this protocol. Importantly from the standpoint of warnings, Dr. Popovich testified that Abbott never warned him that Humira could cause or contribute to the development of lymphoma.

Dr. Popovich additionally states that he provided Plaintiff with a videotape, provided to him by an Abbott/Humira sales person, in order to inform her about the drug. He agrees the videotape said nothing about any risk of lymphoma or other malignancies. Moreover, during his second

[1] The Court has previously contemplated and written extensively on both the learned intermediary doctrine and §82.007 CPRC. Therefore, Plaintiffs will not belabor the law herein, but rather focus on the evidentiary record

[2] HERO stands for *Humira Efficacy Response Optimization Study in Subjects With Active Rheumatoid Arthritis* (HERO) clinical trial. Ex. A at 3 (Investigator's Agreement) [FILED UNDER SEAL][hereinafter "FUS"]. HERO has been described in Plaintiff's Motion for Relief [Doc. 83].

deposition, when he juxtaposed the "informed consent" language about malignancies (that was provided to Plaintiff) with internal Abbott correspondence to its sales representatives before Humira was prescribed for Plaintiff, Dr. Popovich concedes that the informed consent document was "**inadequate.**" Compare Ex. C (informed consent document) at 5 with Ex. D (October 2004 letter to sales representatives)[FUS]. In light of this evidence, it is clear that there was no legally adequate warning about the known association between Humira and lymphoma to *either* Dr. Popovich or to Plaintiff. Thus, the Court can hold the warning to be inadequate as a matter of law.

Moreover, the Court need not speculate about what Dr. Popovich would have done differently *if* Abbott had simply told him what it was telling its own sales representatives at the same time: "If I had known that there is a definite association of the drug with lymphoma, I would not be prescribing the drug." Ex. E at 216:8-14 (Depo of Jovan Popovich, M.D.).

Under the authorities set forth below, Plaintiff believes that Dr. Popovich's failure to inform Plaintiff about this risk, and his affirmative representation to her that the risk profile was "like aspirin," are imputable to Abbott under long standing principles of Texas agency law. Therefore, as a practical and legal matter, there was no "intermediary" whatsoever.

However, even assuming *arguendo* that Dr. Popovich was an, objective, uncompromised "learned intermediary," Abbott's failure to tell him what it was telling its own sales people about the definite association between all TNF blockers, including Humira, and lymphomas, and its insistence that he use an "inadequate" informed consent in conjunction with an inadequate video to communicate risks to Gayathri Murthy, establish a failure to warn as a matter of law. And it does so even under the Texas Supreme Court's stringent opinion in *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012), reh'g denied (Aug. 17, 2012).

Abbott has argued that its labeling and warnings are presumptively adequate under §82.007 of the CPRC. However, the Texas Legislature has provided two relevant exceptions to the statutory presumption of adequacy, both of which apply in this case. They are (i) off-label promotion and (ii) off-label use. Because the testimony of Dr. Popovich reveals that Abbott was encouraging the use of Humira for "early RA" and was making no effort to distinguish severity vice duration, the drug was promoted to him for use "off-label." As Abbott's clinical trial agent, this conduct is attributable to Abbott. Thus, the statutory exceptions provided in Section §§82.007(b)(3)-(4) of CPRC are applicable in this case. Summary judgment is therefore appropriate on any purported defense under Section 82.007.

Accordingly, pursuant to Rule 56, FED. R. CIV. P., the Court should hold, as a matter of law, that Abbott failed to communicate legally adequate warnings about the risk of Humira and lymphoma in this case and that Section 82.007 is either inapplicable or rebutted. The Order granting partial summary judgment should narrow the issues for trial in the tort case[3] to the following:

**Issues for Trial**

**(1)** Was Humira a proximate cause of Gayathri Murthy's lymphoma?

**(2)** If so, what damages should be awarded to her under Texas law?

**Statement of Undisputed Material Facts**

1. Humira was prescribed to Plaintiff on January 17, 2005 by her rheumatologist, Dr. Jovan Popovich. Ex. F at 7 (Plaintiff's Medical Records). At the time of this prescription, the only approved FDA "indication" was for "adult patients **with moderate to severely active** rheumatoid arthritis **who have had an inadequate response to one or more DMARDS**."[4] Ex. G at 7 (July 30,

[3] As the Court is undoubtably aware, Plaintiff also has made claims sounding in contract.

[4] DMARDS are Disease Modifying AntiRheumatic DrugS.

2004 Label) (emphasis added). At the same time that Dr. Popovich prescribed the Humira to Plaintiff, she was enrolled in HERO. Ex. C.

2. The inclusion criteria for HERO required that only patients with moderate to severe rheumatoid arthritis ["RA"] be enrolled. Ex. H at 21 (Clinical Study Protocol)[FUS]. Neither the FDA approved indication, nor this specific clinical trial, allowed for the use of Humira in "early" RA patients or those with mild symptoms. Ex. G at 7; Ex. H at 21. Importantly, the FDA approved indication required the patient to have tried and *failed* DMARD therapy. Ex. G at 7. Thus, before a patient could use Humira, that patient had to try a lesser therapy without benefit.

3. In the months proceeding Plaintiff's Humira prescription, Abbott's sales representatives made several calls on Dr. Popovich during which they encouraged him to prescribe Humira "off-label" for "early" RA patients. For example, on June 30, 2004, Abbott sales representative Cedric Fuller asked Dr. Popovich if he was also using Humira for "early RA." Ex. I at line 54 (Call Notes)[FUS]. Later that week, Mr. Fuller told him to "try" Humira off-label for his patients who suffered from "early RA." *Id*. at line 55. At the same time, Mr. Fuller was ominously telling Dr. Popovich that both RA and the DMARD methotrexate ["MTX"] were "harmful." Ex. I at line 51;[5] Ex. J at 45:11-46:5 (Depo of Cedric Fuller)[FUS].

4. On August 5, 2004, Dr. Popovich signed an Investigator's Agreement to serve as a principle investigator in Abbott's HERO. Ex. A at 3. As an investigator, Dr. Popovich was selected by Abbott to conduct the clinical trial on Abbott's behalf. Ex. B at 95:24-96:3 [FUS]. Dr. Popovich's contract stated that Abbott would *pay him* to screen patients and prescribe Humira. Ex. K at 2; 9 (Clinical Study Agreement)[FUS]. The contract provided for a $300 fee for simply screening a patient for Humira, a higher, $1,000 fee if the doctor screened the patient but the patient

[5] During a sales call to Dr. Popovich on May 11, 2004, Mr. Fuller advised Dr. Popovich that "Disease is very harmful on the body alone, MTX is harmful." *Id.*

was excluded from the study at baseline, and a $2,000 fee for each patient that was enrolled and who completed the 12-week study. *Id*. at 9. The total compensation under the provision 7(a) of the contract could be up to $42,000, which is above the $25,000 "materiality" threshold contained in Dr. Popovich's Financial Disclosure Certification. Ex. L at 1 (Financial Disclosure Certification)[FUS].

5. Then, less than three weeks after agreeing to be an Abbott investigator, on August 25, 2004, Dr. Popovich saw Plaintiff for the first time. He was the first rheumatologist to ever see Plaintiff. Ex. E at 123:5-123:8. And, yet, on that date, there was "not enough evidence" for him to diagnose Plaintiff with inflammatory polyarthritis, which Dr. Popovich states is another way of saying RA. *Id.* at 123:11-123:20; Ex. F at 1.

6. Five days later, on August 30, Abbott sales representatives were in Dr. Popovich's office again, recommending and promoting the use of Humira in "early RA" patients." Ex. I at line 56. In the same call note the sales representative writes that Dr. Popovich began discussing the HERO trial in an "excited" fashion. *Id.* The Abbott representative then asked Dr. Popovich to use Humira for his RA patients that "do not fit the Study [HERO] criteria." *Id*. In other words, the representative recommended or promoted that Dr. Popovich include patients in the HERO study that do not qualify as having moderate to severe RA. Such use of Humira is "off-label" as the FDA approved indication at that time was for patients with "**moderate to severely active** rheumatoid arthritis **who have had an inadequate response to one or more DMARDS**." Ex. G at 7.

7. During his first deposition, Dr. Popovich confirmed that Humira sales reps were recommending and promoting the use of Humira in early RA patients:

> Q. Do you remember that the general sales presentation, if you will, by this point in time was, Hey, we want you to try it [Humira] earlier on?
>
> A. I think that that could be said.

Ex. E at 39:14-39:20.

8. He confirmed in his second deposition that Abbott sales representatives were encouraging him to use the drug earlier in the treatment of his patients. *Id.* at 226:10-19. He has no specific recollection of Abbott's sales representatives making any distinction between disease severity and disease duration. *Id.* at 226:24-227:9. But he distinctly recalls the sales representatives encouraging him to use the drug early in treatment. *Id.*

9. Less than a month later, on September 22, 2004, Dr. Popovich diagnosed Mrs. Murthy with RA, and began her on a traditional DMARD therapy, MTX, that was mandated by the standard of care and the FDA as a precursor to Humira. *Id.* at 123:24-124:3; Ex. G at 7. Dr. Popovich confirmed in his second deposition that Plaintiff's RA was neither long-standing nor severe. Ex. E at 170:12-25.[6] In three subsequent visits that same fall, Dr. Popovich documents that Plaintiff was tolerating the methotrexate "relatively well," and that it was having a therapeutic effect. Ex. E at 123:24-124:3. In records dated September 22, 2004, Dr. Popovich states that Plaintiff's condition remains "unchanged compared to the visit on 08/25/2004" when he was unable to diagnose Plaintiff with RA. Ex. F at 1. In addition, on examination of Plaintiff, Dr. Popovich states "the musculoskeletal system showed no pain to range of motion of the neck, shoulders, elbows, hands, or wrists. There was minimal soft tissue swelling at the third MCP on the right and second and third MCP on the left without warmth, redness, or tenderness to palpation. There was no tenderness to palpation of the PIP or DP joints." *Id.* at 1.

10. Throughout the rest of 2004, Plaintiff's RA continued to be mild. In fact, her condition improved. Ex. M at 106:17-107:3 (Depo of Gayathri Murthy). On the October 25, 2004 visit, Dr. Popovich writes that Plaintiff's condition remains "unchanged compared to the visit on 08/25/2004," and that she was "feeling better" and denied "side effects" from the methotrexate. Ex.

[6] Dr. Aileen Pangan, Abbott's study designated physician, more *anon*, for HERO agrees that Plaintiff's RA was neither severe nor long-standing. Ex. B at 141:9-16; 141:22-142:3 (Depo of Dr. Aileen Pangan).

F at 3. At her next visit on December 6, 2004, Dr. Popovich again writes that her condition remains "unchanged compared to the visit on 08/25/2004" and that "she presents today doing well" and once again denies "side effects" from the methotrexate. *Id*. at 5.

11. Notwithstanding the fact that Plaintiff was doing well on methotrexate and had mild RA symptoms,[7] on January 17, 2005, Dr. Popovich prescribed Humira for her and enrolled her in the HERO clinical study even though she did not fit the study inclusion "criteria" because, as her records show, she did not suffer from "moderately to severely active RA." *Id*. at 7; Ex. H at 21. Nor had she failed DMARD therapy.[8] Under the payment schedule set forth in his agreement with Abbott, Dr. Popovich was to be paid $2,000 for prescribing Humira to Plaintiff and keeping her on it for the entire twelve week period of the study. Ex. K at 2; 9.

12. In response to questions from Abbott's counsel in his July 30, 2012 deposition, Dr. Popovich confirmed that he told Plaintiff that Humira was like "aspirin" with respect to the dangers of side effects used this very analogy. Ex. E at 79:8-80:1. He also confirmed that the only specific "warning" he gave Plaintiff about lymphoma was the following, as contained in the HERO Consent to Participate agreement that Plaintiff signed that day:

> Occasionally (about 2%), various types of cancer including lymphoma (cancer of lymph node) are observed in subjects taking adalimumab. The relationship of adalimumab with these cancers is currently unknown.

Ex. E at 124:4-125:5; Ex. C at 5.

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[7] Plaintiff's medical records on this date indicate she had no stiffness in the morning, warmth, or redness. *Id.* at 9. Further, she also denied any pain at night, difficulty dressing or grooming, and no problems with buttons, cutlery, or writing. *Id*. She had no new complaints as compared to any of her other previous exams. *Id.* Her only consistent complaints, which were not new, was occasional difficulty with stairs and opening jars. *Id.* Again, none of these were new complaints or worsening symptoms compared to September 2004.

[8] *See also* Plaintiff's Supplemental Exhibit in Support of Plaintiff's Opposed Motion for Relief from Judgment, and the attached exhibits thereto. [Doc. 88]. Therein, Dr. Eric Gershwin, Chair of Rheumatology and Immunology at UC Davis, confirms that Plaintiff did not meet the HERO study inclusion criteria as there was no significant evidence to diagnose her with moderate to severely active rheumatoid arthritis. Ex. A to Doc. 88 at 2. Further, Plaintiff had not failed DMARD therapy. *Id.*

13. However, to assist her with her treatment decision, Abbott provided Dr. Popovich a videotape to provide to patients. The videotape was provided to Dr. Popovich by Abbott's sales representatives. Ex. E at 177:6-179:2. Dr. Popovich confirms he gave the video to Plaintiff. *Id.* It was designed to be given directly to patients as a "tool to help inform" them. *Id.* Based on Dr. Popovich's understanding, the intent of the video was to help patients make a "decision one way or the other" as to whether to take the drug. *Id.* Dr. Popovich believed that all the information in the video would be fair and accurate because he felt that the FDA required the drug company not to distribute materials that were not fair and accurate. *Id.*

14. Dr. Popovich further describes the video as informational with respect to the benefits of Humira. *Id.* at 179:24-182:9. After watching the video in deposition, Dr. Popovich additionally describes how the video portrays: 1) the destructive nature of RA, 2) how depressing it is to patients to have RA, 3) how scary it is to patients to have RA, 4) the loss of functionality from RA, 5) the inability to interact with grandchildren, 6) the struggle with daily activities due to RA, and 7) the ease with which Humira can be injected. *Id.* He further confirms that the video equally describes a multitude of Abbott provided patient benefits, to include a toll-free hotline, financial assistance for patients who cannot afford Humira, and injection assistance. *Id.*

15. However, although the video does make mention of some possible side effects, Dr. Popovich confirmed that it says nothing about lymphoma, much less any risk of lymphoma due to the use of Humira. *Id.* It further says nothing about any sort of malignancies or risks thereof. *Id.*

16. According to Dr. Popovich: "In my opinion, [the video] would be inaccurate because [sic] does not mention any malignancies or lymphoma." *Id.*

17. Plaintiff watched this videotape and found it to be "impressive." Ex. M at 67:6-68:1; 111:12-112:18. Based on the video, she "liked the drug" and the way it portrayed patients, and felt

"comfortable." *Id.* It helped convince her to agree to take Humira. *Id*. at 111:24-112:18. She viewed the video around the time of her informed consent discussion and inclusion into HERO. *Id*. Although due to the passage of time Plaintiff was not 100% certain as to when she viewed the video, she thought that she most "probably" did so prior to the informed consent discussion. *Id.* at 67:6-68:1. *See also Id.* at 39. It also helped her stay on the drug after she began Humira therapy. *Id.* And it said nothing to her about any risk of malignancies, much less lymphoma. *Id.* at 113:1-7.

18. Prior to treating Plaintiff, no one from Abbott ever warned Dr. Popovich that it was biologically plausible for Humira to cause or contribute to the development of lymphoma. Ex. E at 189:11-192:16. Nor did Abbott ever inform him that there was a "reasonable association" between the use of Humira and lymphoma. *Id.* Dr. Popovich would expect Abbott to tell him if they believed either biologic plausibility or reasonable association *vis-à-vis* Humira and lymphoma. *Id.*

19. Abbott equally did not inform Dr. Popovich that the drug could possibly cause or contribute to the development of lymphoma. *Id*. While Dr. Popovich was aware of an association between the use of Humira and lymphoma, he was (and is) simply unclear on whether the drug plays any role or contributes to the development of lymphoma. *Id.*

20. In contrast, Abbott's Rule 30(b)(6) clinical trial designee and Divisional V.P. for Humira, Dr. John Medich, believes it is biologically plausible that Humira can cause lymphoma:

> Q: ..."It is biologically plausible that TNF antagonists, which are novel immunomodulatory agents, might produce significant adverse effects including an increased risk of malignancy." Do you agree with that sentence?
>
> A: It is possible.
>
> Q: Okay. And is it biologically plausible?
>
> A: It is biologically plausible.

Ex. N at 64:9-18 (Depo of Dr. John Medich taken in *Jones, et al v Abbott*)[FUS].

21. Abbott rheumatologist and 30(b)(6) designee, Dr. Aileen Pangan, also believes it is biologically plausible for Humira to cause lymphoma:

> Q: Is it fair to say that from the time Humira was launched at the end of 2002 forward, that there was a reasonable biologically plausible relationship or association between Humira and the development of lymphoma?
>
> A: Yes.

Ex. O at 64:9-64:18 (Depo of Dr. Aileen Pangan taken in *Jones, et al v. Abbott*)[FUS].

22. Dr. Pangan also believes that there is in fact a reasonable association between lymphoma and Humira:

> Q: Okay. But Humira is reasonably associated with a number of adverse events, is it not?
>
> A: Yes.
>
> Q: Lymphoma?
>
> A: Yes

*Id.* at 67:11-14.

23. Dr. Medich admitted in deposition that Humira suppresses the immune system and could cause cancer. Ex. N at 51:5-52:5. None of this information regarding biologic plausability, reasonable association, or actual risk, was shared with Dr. Popovich. Ex. E at 189:11-192:16.

24. But internally, Abbott *was* sharing this information with its sales force. Sales representative Fuller, admitted in deposition that he was trained on Humira's side effects and how to handle questions from doctors about these side effects. Ex. J at 13:10-23. Mr. Fuller testified that he was trained that lymphoma was a side effect of Humira. *Id*. at 13:24-15:9. He recalls that Abbott told him that there was a lymphoma risk in taking the drug during his training. *Id.* at 15:10-25.

25. Additionally, in October 2004, the very time period in which Dr. Popovich was first treating Plaintiff, Abbott sent a confidential letter to its sales representatives about this issue stamped

in all capital letters "FOR REPRESENTATIVE EDUCATION ONLY." Ex. D. In this letter, Abbott expressly told its sales force that "All TNF antagonists are associated with an elevated risk of lymphoma." *Id.* Although TNF inhibitors were thought to be "possibly associated" with a lymphoma risk, Dr. Popovich believes this statement to its sales force described an understanding of risk that was altogether different than his understanding. Ex. E at 210:1-213:9. It concerned him that Abbott was aware of an actual association (vice a "possible" one) and not telling doctors it knew about this distinction. *Id.* He "definitely" wanted to know this information. *Id.* But he did not at the time he treated Plaintiff. *Id.* Dr. Popovich made this crystal clear in deposition:

> Q: So, as we sit here today- - as I understand your testimony, no one from Abbott, either sales representative or an informative dear doctor letter, any type of communication, has ever informed you that the use of Humira can cause or contribute to the development of lymphoma in a Humira patient.
>
> A: No one had told me that.

*Id.* at 191:17-192:1.

26. Moreover, despite awareness that previous Abbott clinical investigators had made clinical judgments that Humira was "probably" causally related to the development of lymphoma in other Humira clinical trial patients, Abbott did not share this information with Dr. Popovich either. *Id.* at 207:9-208:1. *See also* Ex. P at 2, 4, 7, 11-12 (Internal Causality Assessments)[FUS].

27. On the other hand, Dr. Popovich heeds warnings from drug companies. Ex. E at 187:21-188:24. He incorporates those warnings in his treatment decisions and passes those warnings on to patients. *Id.* Specifically, if Dr. Popovich had been warned about an elevated risk of lymphoma, he would have told Plaintiff. *Id.* at 215:6-13. But he did not because, in Dr. Popovich's own words, "I cannot tell something that I don't known." *Id.* at 215:6-18.

28. Because Abbott was aware of this actual risk and did not warn Plaintiff or him, Dr. Popovich believes the risk information he gave to Plaintiff in the informed consent document was

"inaccurate." *Id.* at 213:10-214:11.

29. To further evidence the preventable nature of Plaintiff's injuries, Dr. Popovich believes he had other treatment options for her. *Id.* at 215:25-216:14. She was early in her RA. *Id.* And most importantly for purposes of this motion, if he had known about a definitive association between Humira and an elevated risk of lymphoma, he would not have prescribed the drug to her: **"If I had known that there is a definite association of the drug with lymphoma, I would not be prescribing the drug."** *Id.* Beyond that, if *Plaintiff* had been informed that Humira was linked to, or associated with, lymphoma, *she* would not have taken the drug. Ex. M at 113:1-18. And it is always the patients choice according to Dr. Popovich. Ex. E at 186:17-187:4.

30. Dr. Popovich was approached by an Abbott sales representative to be a company clinical investigator. Ex. E at 171:1-20. Abbott VP, Dr. John Medich, states that it is "inappropriate" for any sales representative to discussing clinical trial work with a physician. Ex. Q at 36:19-37:9, 38:7-10 (Depo of John Medich taken in *Pletan v. Abbott*)[FUS] (...they're not to engage investigators..."). He also believes it inappropriate for a sales representative to discuss details of a potential clinical trial with a clinical investigator. *Id.* at 70:12-23. This is precisely what Abbott's sales representatives did in this case. Ex. E at 171:1-20.

31. Per the HERO study-designated physician,[9] Dr. Eileen Pangan, HERO was designed by Abbott and, at least in part, focused on the early phase of the treatment of RA. *Id.* at 15:17-23, 24:14-25. To its benefit, Abbott also published the data from HERO and presented it in conferences. *Id.* at 26:8-27:3. Abbott equally chooses the investigator cites. *Id.* at 30:21-31:14.

[9] The HERO study-designated physician was the individual within Abbott who was "overseeing the development of the [study] protocol," "primarily responsible for evaluating any kind of medical issues that develop during the trial," and "responsible in making sure that, from a medical-scientific point of view" that the data was appropriately analyzed. Ex. B at 19:13-20:3. Dr. Pangan equally helped finalize the HERO protocol. *Id.* at 20:4-16.

32. Dr. Popovich was required to follow a HERO clinical protocol that "specifically regulated what has to be done" by a clinical investigator. Ex. E at 172:2-172:18. Abbott provided Dr. Popovich all study-related materials, the "blinded" study medication, the protocol, and the informed consent document. Ex. B at 96:4-19. According to Dr. Pangan, Abbott has to rely upon these investigators because it cannot conduct clinical trials without them. *Id.* at 98:18-99:4. Per Dr. Pangan, the study investigator is Abbott's conduit to the patient. *Id.*

33. Dr. Popovich understood that he was required to strictly adhere to the HERO protocol. Ex. E at 175:14-175:17. He had no control over how to conduct the HERO study. *Id.* at 176:21-176:24. Further, under the protocol Abbott controlled all details of how the study was conducted by Dr. Popovich, including study objectives, study medication, what forms were required to be completed, how often to see patients, and what informed consent document would be provided to study participants like Plaintiff. *Id.* at 172:19-173:4; 175:14-175:22. And in fact, Dr. Popovich provided Plaintiff with informed consent document provided to him by Abbott. *Id.* at 197:25-198:3. He provided Plaintiff with the malignancy warning contained in the informed consent, and could not deviate from that malignancy warning. *Id.* at 198:8-198-21.

34. To be clear, it is indisputable that this warning information that he provided to Plaintiff was provided to him by Abbott. *Id.* at 198:8-21. He provided this information to Plaintiff because Abbott provided this warning to be given to her. *Id.* The malignancy warning in the informed consent document that Dr. Popovich could not deviate from did not give the entirety of the known information about Humira's malignancy risk profile. *Id.* at 202:6-202:16. According to Dr. Popovich, this included the "inaccurate" statement "the relationship of adalimumab with these cancers is currently unknown." *Id.* at 213:13-214:11. Plaintiff signed this informed consent and decided to take the drug on January 17, 2005, after Dr. Popovich discussed with her the risks and

benefits of the drug solely based on the informed consent document created by Abbott, and watching the videotape. *Id.* at 217:14-217:25.

35. Unfortunately, the warning information that Abbott provided to him to give to HERO clinical patients, including what was given to Plaintiff, said nothing about how many lymphomas were seen in Abbott's clinical trials or about the rates in which lymphoma was seen in these trials. *Id.* at 199:9-202:2. Additionally, it also did not tell them that in these patients more cases of lymphoma were seen in TNF-treated patients than non-treated patients, nor did it describe who was most at risk for developing lymphoma. *Id.* Equally silent was the "warning" about the fact that no placebo treated patients developed lymphoma and that only Humira treated patients developed lymphomas in the trials. Dr. Popovich believes the informed consent document does *NOT* convey all the risk information about lymphoma to patients. *Id.* at 202:12-16.

36. Dr. Popovich provides patients with the current, more specific warnings today. Ex. E at 16:20-17:6. In his deposition, Dr. Popovich testified that he would have done the same back in 2004 *if* Abbott had provided him with a more specific warning. *Id*. at 127:2-127:25. As mentioned earlier, Dr. Popovich expressly stated that if Abbott had warned him the drug could cause or contribute to the development of lymphoma, he would not only have warned patients, he would have expressly warned Plaintiff. *Id.* at 194:22-195:15.

37. Dr. Popovich believes Plaintiff to be an active participant in her healthcare decisions. *Id.* at 187:16-20. In sworn deposition testimony, Plaintiff confirms that had she been informed that she was being prescribed the drug off-label or outside the express HERO inclusion criteria she would have never taken the drug. Ex. M at 113:1-113:9. Also, had she been told that Humira was linked to or caused cancer she would never have taken the drug. *Id*. at 113:10-113:18.

38. The minimization of the part of the indication that requires failure of a lesser therapy before Humira can be used and use in milder forms of disease are consistent themes in Abbott's aggressive marketing tactics. And this is, in fact, off-label promotion. The Court need look no further than the FDA's action with regarding to Abbott's marketing of Humira for psoriasis. Upon its launch for the treatment of psoriasis in January 2008, Abbott "prominently" touted Humira as "[n]ow approved for moderate to severe chronic plaque psoriasis." Ex. R at 3 (FDA DDMAC Letter). In December 2008, the FDA's Division of Drug Marketing, Advertising, and Communications ["DDMAC"] found this proclamation made to physicians and patients to be "misleading" because Abbott failed to further relay that the approved indication was not for *all* psoriasis patients with moderate to severe psoriasis, but only a select group of them:

> This claim misleadingly suggests that HUMIRA is approved for *any patient* with moderate to severe chronic plaque psoriasis. However, HUMIRA is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, *and when other systemic therapies are medically less appropriate*.

*Id*. at 3 (emphasis added).

39. Beyond the above, additional discovery has revealed that Abbott employed other creative ways to promote Humira for off-label uses to Dr. Popovich. Mr. Fuller described how he would periodically bring an Abbott employed "clinical science liason" with him to meet with Dr. Popovich (and other Houston area physicians). Ex. I at line 61/64; Ex. J at 69:18-74:20. Mr. Fuller would bring this Abbott employed rheumatologist with him on sales calls to discuss forthcoming, off-label indications and off-label indications under study. *Id.* Mr. Fuller brazenly and unapologetically proclaims that this conduct was not off-label promotion despite his coordination of the meeting and that the non-prescribing doctor was being paid by Abbott to discuss non-approved indications. *Id.* Mr. Fuller specifically coordinated discussions for non-approved indications with

Dr. Popovich concerning both psoriatic arthritis and Crohn's disease. *Id.* He readily admits these were off-label discussions. *Id.* And he readily admits that he orchestrated meetings with other physicians before and after the meetings with Dr. Popovich.

## Arguments and Authorities

### I. SUMMARY JUDGMENT IS WARRANTED ON ABBOTT'S LEARNED INTERMEDIARY DEFENSE.

#### A. The learned intermediary doctrine is not applicable in this case.

1. The videotape viewed by Plaintiff is direct-to-consumer promotion and, as such, meets an exception to the doctrine. Undoubtedly when Abbott files its own Motion for Summary Judgment based on the learned intermediary doctrine, it will highlight the recent Texas Supreme Court opinion of *Centocor,* 372 S.W.3d 140, and argue that this doctrine has now been conclusively and comprehensively adopted in this state. But, such a notion would be incorrect. For in *Centocor*, the Texas Supreme Court repeatedly stated that it was not "deciding whether Texas law should recognize any of the exceptions to the learned intermediary doctrine" and that "[w]e acknowledge that some situations may require exceptions to the [doctrine]." *Id.* at 162, 164. The facts of *Centocor* simply did not lend themselves to such an analysis in the court's judgment. *Id*. However, the facts of this case do lend themselves to such an exception.

Dr. Popovich, the prescribing physician, gave Plaintiff a videotape touting the benefits of Humira prior to her starting the drug. Statement of Undisputed Material Facts [hereinafter "SUMF" at ¶¶ 13-17 (..."I think he gave me a video cassette to look at it. So I took it home and I looked – I think it was before he started me on the study."). Plaintiff found this video to be "impressive" and convinced her it helped "RA." *Id.* She remembered that the video helped her "like" the drug. *Id.* When first asked by defense counsel if the video was given to her before she was given the

"informed consent form," Plaintiff said "probably." *Id.*[10]

Although the Texas Supreme Court reaffirmed its general adherence to the *rule* of the learned intermediary doctrine in Centocor, it expressly left the door open to adopt one or more of the *exceptions* that have been adopted in other jurisdictions. *Centocor*, 372 S.W.3d at 162.[11] The facts of *Centocor* simply did not lend themselves to this analysis according to the court. *Id.* However, in this case, unlike *Centocor* where the plaintiff stated she only saw the video after she began her Remicade infusion and the video in question principally dealt with the infusion process, Plaintiff clearly testified on multiple occasions she most likely saw the video before her injections. *Id.* at 163. Additionally, in this case, unlike *Centocor*, the advertising in question said absolutely nothing about any risk of malignancy, but rather, was focused on the benefits of Humira. It was inaccurate about risks of lymphoma according to Dr. Popovich. SUMF at ¶ 16.

An additional evidentiary fact distinguishing this case from *Centocor* is that the Humira video also persuaded Plaintiff to *continue* her Humira injections. SUMF at ¶ 17. It gave her confidence in the medication and made her comfortable in its continued use. *Id.* And as Plaintiff's expert has opined, with respect to a malignancy side effect, it is the continued exposure that causes the harm. Ex. S at 33:1-16; 34:4-11 (Depo of Dr. Dean McCracken).

Dr. Popovich confirms that it is always the patient's decision as to whether they want to take a drug or not. SUMF at ¶¶ 13, 18. Thus, it was Plaintiff's decision as to whether or not to take Humira in the first place as well as to continue its use. *Id.* And the video persuaded her to do so.

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[10] Despite Plaintiff answering on multiple occasions that she had most likely seen the video before her first injection, Abbott's counsel continued to press her on the issue. And at one point, she answered that she could not remember clearly. *Id.* Nevertheless, such an answer still does not diminish the fact that she answered unequivocally on multiple occasions that she watched the video prior to her first injection.

[11] *See e.g., Vitanza v. Upjohn Co.*, 214 F3d 73, 78 (2d Cir. 2000) certified question answered, 257 Conn 365, 778 A2d 829 (2001). The Connecticut Supreme Court's opinion recognizes six different common law exceptions to the defense, including a direct-to-consumer advertising example. *Accord Perez v. Wyeth Laboratories, Inc.*, 161 N.J. at 21, 734 A.2d 1245; Restatement (Third) of Torts: Products Liability § 6.

Plaintiff will not belabor all the arguments in favor of a direct-to-consumer ["DTC"] exception to the learned intermediary doctrine as this Court has previously written extensively on the inconsistencies between the two. *See* Order dated 3/6/12 at 15-19. Suffice to say, this case is factually distinguishable from *Centocor*. And because the Texas Supreme Court has not addressed nor prohibited a DTC exception to the doctrine, the facts of this case warrant an *Erie* prediction that Texas would allow an exception in these circumstances[12] The Court should grant this motion.

2. There is no learned intermediary because Dr. Popovich was Abbott's agent.

In its Order dated December 3, 2012, the Court described the applicable Texas law regarding agency. [Doc. 114 at 8]. As the Court noted in quoting the Fifth Circuit, "Under Texas Law, '[a]gency is the consensual relationship between two parties when one, the agent, acts on behalf of the other, the principal, and is subject to the principal's control.' To prove agency, evidence must establish that the principal has both the right: (1) to assign the agent's task; and (2) to control the means and details of the process by which the agent will accomplish that task." *Indian Harbor Ins. Co. v. Valley Forge Ins. Grp.*, 535 F.3d 359, 364 (5th Cir. 2008)(internal citations omitted). The use of words or phrases like "independent contractor" is not dispositive. Rather, the Texas Supreme Court has repeatedly stated that the right of control is the "supreme test" in establishing an agency relationship. *State Farm Mut. Auto. Ins. Co. v. Traver*, 980 S.W.2d 625, 628 (Tex. 1998) (citing *Newspapers, Inc. v. Love*, 380 S.W.2d 582, 588, 590, 598 (Tex. 1964)); *Accord St. Joseph Hosp. v. Wolff*, 94 S.W.3d 513, 542 (Tex. 2002).

"Under Texas Law, an owner or general contractor can be held vicariously liable for physical harm caused by an independent contractor 'if the employer controls the details or methods of the

[12] In another Humira case pending in federal court in Tennessee, the federal district judge has certified a question to the Tennessee Supreme Court as to whether it would recognize exceptions to the learned intermediary doctrine for direct payments to a prescribing physician. Order attached as Ex. T.

independent contractor's work to such an extent that the contractor cannot perform the work as it chooses.' This 'control must relate to the activity that actually caused the injury.'" *Indian Harbor Ins. Co. v. Valley Forge Ins. Grp.*, 535 F.3d 359, 364-65 (5th Cir. 2008)(internal citations omitted). *See also Cardinal Health Solutions, Inc. v. Valley Baptist Med. Ctr.*, 643 F. Supp. 2d 883, 888 (S.D. Tex. 2008)("Further, the principal's extent of control over the details of accomplishing the assigned task primarily distinguishes the status of independent contractor from that of an agent.").

The question of whether a principal-agent relationship exists is a question of law for the Court if the facts are undisputed. *Ross v. Tex. One P'ship*, 796 S.W.2d 206, 210 (Tex. App.-Dallas 1990, writ denied). Consequently, it is one that is appropriate for summary judgment given the clear record facts before the Court supporting a finding of law that Dr. Popovich was Abbott's agent.

Abbott controlled every single task that Dr. Popovich performed and the details of the manner in which he performed it. Dr. Popovich made clear that not only did Abbott create and provide to him the "set of rules" that he "had to follow from the inception of the study...to the end of the study" but that he was additionally "specifically regulated" in following these rules. SUMF at ¶¶ 30-32. Dr. Popovich stated that the protocol "controlled all the details of how the study was to be performed." *Id.* Further, Abbott defined the study objectives, the medication, the forms he was required to fill out, the informed consent that he was to provide to patients, the questions he had to ask his patients, the various clinical measures he had to use, the *doses* of medication that the patients would take, the timeline in which he was to perform these clinical measures, when he would see patients, how often he would see patients, the study groups, and the confidentiality of the study. *Id.*

Moreover, this was initially a *blinded* clinical study. *Id.* Thus, only Abbott knew who was actually receiving the drugs at inception and who was receiving placebo. *Id.* Abbott was the party that assigned (randomized) Plaintiff to actually get the drug. Dr. Popovich did not know: "Whoever

is running the study does not know whether a patient is getting the drug or placebo." *Id.* Yet, despite Abbott's assignment of patients to the various groups for Dr. Popovich's treatment, and despite him not knowing whether the patient was "on or off" study drug at inception, Dr. Popovich was still required to strictly adhere to all facets of the clinical trial protocol. *Id.*

In his own words, "[t]he protocol would dictate what I have to do as an investigator." Ex. E at 176:8-15. But, Dr. Popovich did not stop there. He confirmed that the protocol "dictated the process" by which he worked and he had no control over how he could conduct the study. *Id.* at 176:16-24. By any fair measure, it is indisputable that Dr. Popovich was Abbott's agent in fact. Any argument that he was an independent contractor is belied by the evidentiary record before the Court.

Because Dr. Popovich was Abbott's agent, then under the law he is not an intermediary, regardless of whether he is or is not "learned." The rationale for the doctrine is utterly absent:

> "The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy."

*Centocor*, 372 S.W.3d 140 *quoting and citing favorably* **RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY** § 6 cmt. b. Holding that Dr. Popovich was not an agent would usurp the underlying basis for Texas Supreme Court's limited adoption of the doctrine in *Centocor*. The court made clear that it is the "learned"intermediary who "understands the risks involved" and the doctrine relies upon him to filter warnings and to exercise the clinical judgment in treatment decisions. However, if there is no independent intermediary under the laws of agency, or the doctor must provide the warnings that the drug company gives him under the terms of the study protocol, then *ipso facto*, the learned intermediary doctrine simply cannot apply because the doctor cannot "stand" between the manufacturer and the patient. *Id.* at 156 citing *Alm v. Aluminum Co. of Am.*, 717 S.W.2d

588, 591 (Tex. 1986). This critical component of the doctrine is missing in this case.

Because Abbott so heavily controlled every single aspect of the physician/patient relationship between Dr. Popovich and Plaintiff, the underlying basis for any application of the learned intermediary doctrine is absent. As such, the doctrine is inapplicable.

**B. Plaintiff's prescribing physician was not adequately warned.** Assuming *arguendo* that the Court undertakes a substantive analysis of the learned intermediary "facts" in this case, which it need not do given the DTC and agency issues discussed in section I.A.2., *supra*, summary judgment is still appropriate in Plaintiff's favor. *Centocor* will undoubtedly be the centerpiece of Abbott's arguments in favor of the application of this doctrine. Our discussion starts there.

In *Centocor*, the court described a two-prong analysis of any discussion of the learned intermediary doctrine. First, if the warning to the prescribing physician was inadequate, the manufacturer remains liable. 372 S.W.3d at 170. Second, the Court must examine whether the inadequate warning was a producing cause of the plaintiff's injuries. *Id.*

Turning to the first prong of the analysis, the Court must examine whether the warning provided to Dr. Popovich was adequate. In this case, it is indisputable that it was not. First, the warning at issue that was given to Dr. Popovich in the informed consent said absolutely nothing about any drug related risk of lymphoma. SUMF at ¶¶ 12; 33-35. Nor did it describe that only Humira treated patients in Abbott's clinical trials developed lymphoma. *Id.*

Second, while Abbott was clearly and indisputable warning its sales force that "all TNF inhibitors were associated with an elevated risk of lymphoma," SUMF at ¶¶ 23-24, it was not sharing this information with doctors like Dr. Popovich. *Id.*; *Id.* at 19. This is significant. For the medical community was concerned about a "possible association" between the use of Humira and lymphoma. *Id.* Doctors were struggling to understand if the drug played a role in the development of lymphoma.

Yet, while doctors, including Dr. Popovich, were grappling with this issue, Abbott sent a confidential memorandum to its sales force describing a very real risk. While Abbott will undoubtedly attempt to minimize the significance of the wording, the difference between "unknown" and "possible" was clearly significant to Dr. Popovich. *Id.* at ¶ 24. Additionally, Abbott's science executives confirmed that Abbott was aware of both a reasonable association, and the biologic plausibility of a causal link, between Humira and lymphoma. SUMF at ¶¶ 20-24. Dr. Popovich was unaware of *any* of this information, although he expected to be told. SUMF at ¶¶ 18-19; 24; 27-28.

In sum, the record is replete with evidence proving that Abbott was aware of a significant amount of safety information regarding lymphoma and Humira that was unknown to Dr. Popovich. When the "warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient." *Centocor*, 372 S.W.3d at 157. Abbott knew of biologic plausibility, definitive association, and that only Humira treated patients had developed lymphoma during its clinical trials. Dr. Popovich was unaware of any of this. More importantly, he unequivocally testified that the risk information of which he was aware was incomplete and inaccurate. By any fair measure this man was utterly uninformed and unwarned about the true risk of Humira causing or contributing to the development of lymphoma. If Humira was **a** producing cause of Gayathri Murthy's lymphoma, Abbott is liable.

**C. Abbott's inadequate warning was a producing cause of Plaintiff's injuries.**

Under *Centocor*, the second prong of the learned intermediary analysis is based in producing cause. Again, although the Court need to get this far, assuming it does, the inadequacy of the warning information was the producing cause of Plaintiff's injuries. Dr. Popovich testified unequivocally that if he had known of an association between Humira and lymphoma, he would not have prescribed the drug. SUMF at ¶¶ 26-28; 35-36. He did not need to prescribe this drug to Plaintiff as she had other

treatment options available to her. *Id.* The inquiry should end there.

But even if the Court desires more, Dr. Popovich was equally clear that he heeds warnings from drug companies. *Id.* And if he had been properly warned, he would have shared that warning with Plaintiff. *Id.* Plaintiff confirms that she would declined this drug if she was warned about a risk of lymphoma. *Id.* Instead, the caveated, confusing, and in some instances in the record nonexistent, warning that was provided to Dr. Popovich and Plaintiff was the reason this drug ultimately entered her system. Plaintiff has satisfied the second prong of the analysis.

## II. SECTION 82.007 CPRC IS REBUTTED IN THIS INSTANCE.

**A. Abbott promoted Humira to Dr. Popovich off label.** As this Court has touched on in its previous Order, Plaintiff has pled at least two possible exceptions to the statutory presumption of Section 82.007 of the CPRC. [Doc. 114 at 6-9]. The law in Texas is clear: "Once evidence contradicting the presumption has been offered, the presumption disappears and is not weighed or treated as evidence. The facts supporting the presumption remain in evidence and can support any reasonable inferences that may be drawn." *Ackermann v. Wyeth Pharmaceuticals*, 471 F. Supp. 2d 739, 749 (E.D. Tex. 2006) *aff'd,* 526 F.3d 203 (5th Cir. 2008) *citing Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993).

The first such plead exception is overpromotion. In his second deposition, Dr. Popovich unequivocally established that Abbott was promoting Humira for an off-label indication. Any fair read of Dr. Popovich's deposition makes clear that he believed the medical community was struggling to determine whether Humira was actually associated with a risk of lymphoma. SUMF at ¶¶ 19; 24-28. And while Abbott was telling its sales force in confidential memoranda and training that there was an actual association and risk, it was not so informing doctors. Rather, what its sales force was communicating to Dr. Popovich was to use the drug for "early RA" and that MTX was

dangerous for patients *Id.* at 23:6-8; 37-38. It made no effort to differentiate disease severity vice disease duration. *Id.* The message was to use the drug early in RA.

Abbott was encouraging Dr. Popovich to prescribe this drug for patients who had a milder form of the disease and simply ignoring the labeling indication that required the patient to have had an inadequate response to DMARD therapy. At the time, the *only* FDA approved indication was for moderate to severe RA patients who had failed traditional DMARD therapy.[13]

And although the Court has written on whether the medical literature draws a distinction between duration and severity, the point is that Abbott cannot legally be "muddying the waters" to its benefit. It must be clear in what it is promoting. The Court has already held that the sales call notes and comments made therein are sufficient to raise a question of fact on overpromotion. *See* Order dated December 3, 2012 at p. 7. Dr. Popovich's second deposition, of which the Court did not have benefit at the time, simply confirms what the Plaintiff already knew. Abbott was encouraging this man to use the drug aggressively in patients, paying him to do so, and was not clearly staying within the bounds of its FDA approved indication.[14] The product was used in Plaintiff in the overpromoted manner and Plaintiff's injuries were causally related to such use.[15] *See* Court's Order of 12/3/12 at 6-8. Moreover, call notes and sales representative testimony confirm that not only were sales representatives improperly discussing clinical trials with Dr. Popovich, but that they were also encouraging him to use this drug in "early RA." SUMF at ¶¶ 6-8; 37-38.

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[13] In fact, the FDA labeled the exact same conduct as off-label promotion when Abbott advertised for a broader use of Humira in psoriasis patients and for minimizing the failure of lesser therapies. SUMF at ¶ 37. Such promotion is directly akin to what Abbott was doing in this case. Abbott plead guilty to the same behavior with its drug Depakote. *See* Plaintiff's Motion for Relief from Judgment at 9-10.

[14] The Court has written at length about its concerns regarding direct payments to treating physicians and the subversive ramifications, even if subconscious, such behavior can have on the doctor-patient relationship. Plaintiff will not belabor the point beyond stating that clearly Dr. Popovich had a financial incentive to include as many patients as possible in HERO and to continue them in the trial for as long as possible. SUMF at ¶ 4.

[15] *See* expert report of oncologist, Dr. Dean McCracken. [Doc. 123].

Thus, the evidence fully supports that not only did Abbott recommend and promote Humira for off-label use (*i.e.,* for mild RA and without DMARD failure), but that Dr. Popovich actually used the drug as recommended and the injuries were caused by such use. *See* CPRC 82.007(b)(3)(A)-(C). As such, the Court should hold as a matter of law that the Plaintiff has established an exception under Section 82.007(b)(3). *See also Lucas v. Abbott Laboratories*, 3:12-CV-3654-B, 2013 WL 2905488 (N.D. Tex. June 13, 2013).

**B. Dr. Popovich prescribed the Humira to Plaintiff as Abbott's agent.** In Section I.A.2., *supra*, Plaintiff chronicled the agency relationship between Abbott and Dr. Popovich. For the same reasons that the learned intermediary doctrine does not apply in this case, so too does Plaintiff rebut the presumptive statute under 82.007(b)(4). Under Texas agency law, the conduct of Abbott's agent is imputed to it and it is vicariously liable. " *Indian Harbor, supra,* 535 F.3d at 364-65 . Thus, under the statute, it is Abbott that actually prescribed the drug to Plaintiff. And it did so for a non-FDA approved indication and thereby caused Plaintiff's injuries, section II.A., *supra*. *See also* Plaintiff's Motion to Vacate [Doc. 38] and exhibits thereto. Under section 82.007(b)(4), the statutory presumption has also been rebutted in this case.

## Conclusion

For all the foregoing reasons, Plaintiff respectfully requests the Court grant her summary judgment on Abbott's learned intermediary and TEXAS CIVIL PRACTICE AND REMEDIES CODE Section 82.007 defenses. Further, the Court should hold that the only issues remaining for trial are:

**(1)** Was Humira a proximate cause of Gayathri Murthy's lymphoma?

**(2)** If so, what damages should be awarded to her under Texas law?

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Respectfully submitted,

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Certificate of Service

I certify that on this 3rd day of July, 2013, Plaintiff's Motion for Partial Summary Judgment has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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